

Re: Vaccines Africa Brief for Congressional Research Services (CRS)

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Summary: This report is a product of the VacSafe Working Group, a group of leading scientists, vaccine and public health experts, and policymakers. Its purpose is to provide an up-to-date overview of the state of SARS-CoV-2 vaccines in Africa (54 countries and two disputed territories). This briefing comes as Africa continues to face major vaccine shortages, amid a high level of community transmission due to the Delta variant. Information included in this briefing is drawn from private and public sources. For broader context, refer to earlier installments of the Vaccines in Africa Brief.

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VacSafe Working Group

Monthly Brief: Congressional Research Services

Vaccines in Africa (54 countries and two disputed territories)

1. SARS-CoV-2 Vaccination Status in Africa

The Our World in Data vaccine tracker reported that as of October 30, 2021, a total of 119.99 million vaccine doses had been administered across the entire African continent. 5.77% of the population has been fully vaccinated, with 2.96% given at least one dose.

According to Our World in Data vaccine tracker as of October 30, 2021, the three best countries by share of people vaccinated are Seychelles (82%), Mauritius (71%) and Morocco (64%). The three lowest are Tanzania (1.4%), Madagascar (1.3%), and Chad (0.97%).

Five countries on the African continent will be able to hit the 40% target by the end of this year: Seychelles, Mauritius, Morocco, Tunisia, and Cape Verde.

2. Vaccine Efficacy, Safety, and Approval

- Moderna has WHO Emergency Use Listing and is approved in Botswana, Ghana, Kenya, Libya, Nigeria, Rwanda and Seychelles.
- Oxford-AstraZeneca (Covidshield) – Africa Regulatory Taskforce (ART) approved. WHO Emergency Use Listing and approved in 32 African countries.
- Serum Institute of India, which is licensed to produce and sell Oxford-Astra Zeneca, has ART and WHO Emergency Use Listing approvals and approved in 14 African countries.
- Pfizer-BioNTech – WHO Emergency Use Listing, FDA approval, and approved in Botswana, Cabo Verde, Kenya, Libya, Nigeria, Rwanda, South Africa and Tunisia.
- Sinopharm – BBIBP-CorV – WHO Emergency Use listing and approved in 24 African countries.
- Sinovac (CoronaVac) – WHO Emergency Use Listing and approved in Algeria, Benin, Egypt, South Africa, Tanzania, Togo, Tunisia, and Zimbabwe.
- Bharat Biotech (Covaxin) – approved in Mauritius and Zimbabwe.
- Gamaleya Institute (Sputnik V) – approved in 19 African countries.
- Gamaleya Institute (Sputnik Light) – approved in Angola, Egypt, Mauritius, and Republic of Congo.
- Janssen/Johnson & Johnson (Ad26.COV2.S) – WHO Emergency Use Listing, ART approved and approved in Egypt, Ghana, Kenya, Liberia, Libya, Madagascar, Malawi, Nigeria, Senegal, South Africa, Tanzania, Tunisia, Zambia and Zimbabwe.

3. Continental Vaccine Acquisition

Seth Berkley from the Global Alliance for Vaccines and Immunizations (GAVI) informed the World Health Summit (WHS) that less than 10% of vaccine dose donations promised to COVAX had been delivered. The People's Vaccine Alliance (PVA) found that 1 out of 7 vaccines pledge by HIC have reached LIC.

On October 15, 2021, President Biden from the US told President Kenyatta from Kenya that the US will make a donation of 17-million doses of the Johnson & Johnson vaccine to the African Union.

Moderna announced that they established a Memorandum of Understanding to sell up to 110 million doses to African Union (AU) states. This would be in addition to the agreement made with COVAX to supply 500 million vaccine doses from the end of Q4 of 2021 through 2022.

4. Vaccine Distribution

South Africa declined to approve Sputnik V vaccine over concerns regarding the increase risk of HIV infection. The vaccine contains a modified form of adenovirus, which officials say was used in HIV vaccine research that failed as it increased the chance of being infected (with HIV) among vaccinated men. This further implies the need of African involvement in drug development. In addition, Namibia also decided to suspend the use of Sputnik days after the drug regulator in South Africa flagged concerns about its safety for people at risk of HIV.

Institut Pasteur of Morocco and Rwanda Biomedical Centre have shown efficiency in rolling out vaccinations in their countries. Morocco has vaccinated more than 80% of its target population, while Rwanda has 25% of its eligible population vaccinated, with a goal of 40% of the population vaccinated by the end of 2021.

5. Vaccine Fill & Manufacturing

Rwanda and Senegal are setting up mRNA manufacturing facilities in an agreement with BioNTech. Construction will begin mid-2022 with each production line producing around 50 million doses a year.

Canada will donate \$15 million to the new technology transfer hub being built in South Africa that will help manufacture mRNA vaccines.

South Africa's Aspen Pharmacare is planning to increase COVID-19 vaccine manufacturing capacity to 1.3 billion doses a year by 2024. Aspen is responsible for the final stages of manufacturing the Johnson & Johnson vaccine. In addition, Afrigen Biologics and Vaccines have scientists reverse-engineering the Moderna vaccine, in hopes of creating vaccine access in Africa. This is backed by WHO, which is coordinating vaccine research and making a training and production hub in South Africa.

Moderna Therapeutics CEO Stéphane Bancel announced that the pharma- and biotech giant is in the process of planning its first African vaccine plant. This new state of the art vaccine manufacturing facility will receive investments for up to \$500 million US Dollar and is expected to produce up to 500 million doses of Moderna's mRNA vaccine. The plant is also expected to produce other Moderna vaccines and will be mostly staffed with local workers. Moderna is currently in the process of identifying which country will be the location of the vaccine plant, with South Africa, Rwanda, and the Senegal being the top candidates.

The four main factors for successful vaccine manufacturing are large scale financing, enhanced research capacity, the commitment from governments to purchase vaccines, and regulatory bodies that meet international standards. Due to the inherent difficulty of biological processes, one of the biggest hurdles to capacity expansion is definitely the manufacture of vaccine batches with consistent characteristics and quality. The transfer of technologies and production processes to facilities in Africa will therefore be particularly difficult. There are specific challenges involved in vaccine production, including process development, process maintenance, lead time, production facilities, equipment, life cycle management, and product portfolio management. A robust and stable manufacturing process and consistent component supplies over decades are key to ensure long life cycle of a vaccine in a market. Failure to manage these risks can result in costly product recalls, suspensions from the market and penalties.

Brazil and Cuba are good learning examples for vaccine production setup by public institutions, while India is an example for private manufacturers. These countries committed to build or shape their own biopharmaceutical manufacturing capacity, initially focused on domestic needs and later expanded to supply international markets through the United Nations Children's Fund (UNICEF) and the Pan American Health Organization (PAHO). Another hurdle are issues with regulatory bodies: A weak National Regulatory Authority (NRA) can create serious difficulties for the national and global business of a vaccine manufacturer. Since 2010, after the World Health Organization (WHO) assessed

NRAs in Africa, there have been great development in African NRAs with some becoming fully functional, though, usually for oversight of pharmaceuticals only and not yet for biopharmaceuticals like vaccines. For vaccines, they depend on WHO pre-qualification program (WHO-PQ) or other competent NRA licensure before local marketing authorization. These aspects must be keenly thought through and covered in the implementation plan of facility establishment and maintenance in Africa. African governments are interested in the establishment of vaccine manufacturing capacity in their countries. However, they would do this only with an external financial and/or technical capacity building support. Thus, they are willing to support an investor at varying levels, such as land, tax incentives, infrastructure provision, and monetary support as a private public partnership. They are also willing to facilitate necessary extra capacity building in their NRA in a form of training or to support collaboration with competent authorities of other countries and the WHO. The latter would help them during an interim phase to cover all regulatory aspects around vaccine manufacturing facility establishment and at the initial stage of product life cycle. All responders expect access to a vaccine at an affordable price and establishment of employment for native experts.

6. Vaccine Licensing/Intellectual Property

The US restated its support for a TRIPS waiver this week, with Dep. Press Secretary Karine Jean-Pierre saying WTO members must “step up [...] and support an intellectual property waiver, and every company must act ambitiously and urgently to expand manufacturing now” according to a White House transcript. “[I]t’s clear that the world must do more in our global COVID-19 response. Other countries must step up, like the United States, and act with more urgency to stamp out ... the virus everywhere,” she added.

Germany’s BioNTech signed an agreement with Senegal and Rwanda to build mRNA vaccine factories in Africa, working with the Institut Pasteur Dakar and the Rwandan government. BioNTech said construction is set to start in mid-2022, and it ultimately plans to transfer manufacturing capacities and know-how to local partners. No dates were specified, and it is unclear how this effort will articulate itself with the WHO-sponsored SA hub (with some worrying the two efforts, if not coordinated, may undermine each other).

7. Emerging Variants

Multiple variants of the virus that causes COVID-19 are circulating globally. In collaboration with a SARS-CoV-2 Interagency Group (SIG), US CDC established three classifications for SARS-CoV-2 variants being monitored: Variant of Interest (VOI), Variant of Concern (VOC), and Variant of High Consequence (VOHC). The US CDC Global Variants Report is tracking the worldwide distribution of four variants, three variants are reported to be circulating in Africa:

- Alpha (B.1.1.7): (VOC) initially detected in the UK, December 2020. Verified in all African countries except: not reported in Comoros, Eritrea, Lesotho, Mali, Sierra Leone, Tanzania, Western Sahara (a disputed territory), Zimbabwe and unverified in Botswana and eSwatini.
- Beta (B.1.351): (VOC) initially detected in South Africa, December 2020. Verified in 43 African countries.
- Delta (B.1.617.2): (VOC) initially detected in India, December 2020. Verified in 41 African countries.
- Gamma (P.1): (VOC) initially identified in travelers from Brazil, January 2021.

The World Health Organization has currently two Variants of Interest (VOI).

- Lambda (C.37), initially detected in Peru, August 2020. Verified in South Africa.
- Mu (B.1.621), initially detected in Colombia, August 2021. Currently, the Mu variant has not been verified to be circulating in Africa.

The category Variant of High Consequence is reserved for variants that have clear evidence that prevention measures or medical countermeasures have significantly reduced effectiveness relative to previously circulating variants. There are currently no variants that rise to the level of high consequence.

There are currently 14 designated Variants Under Monitoring, including C.1.2, first detected in South Africa, September 1, 2021.

Appendix

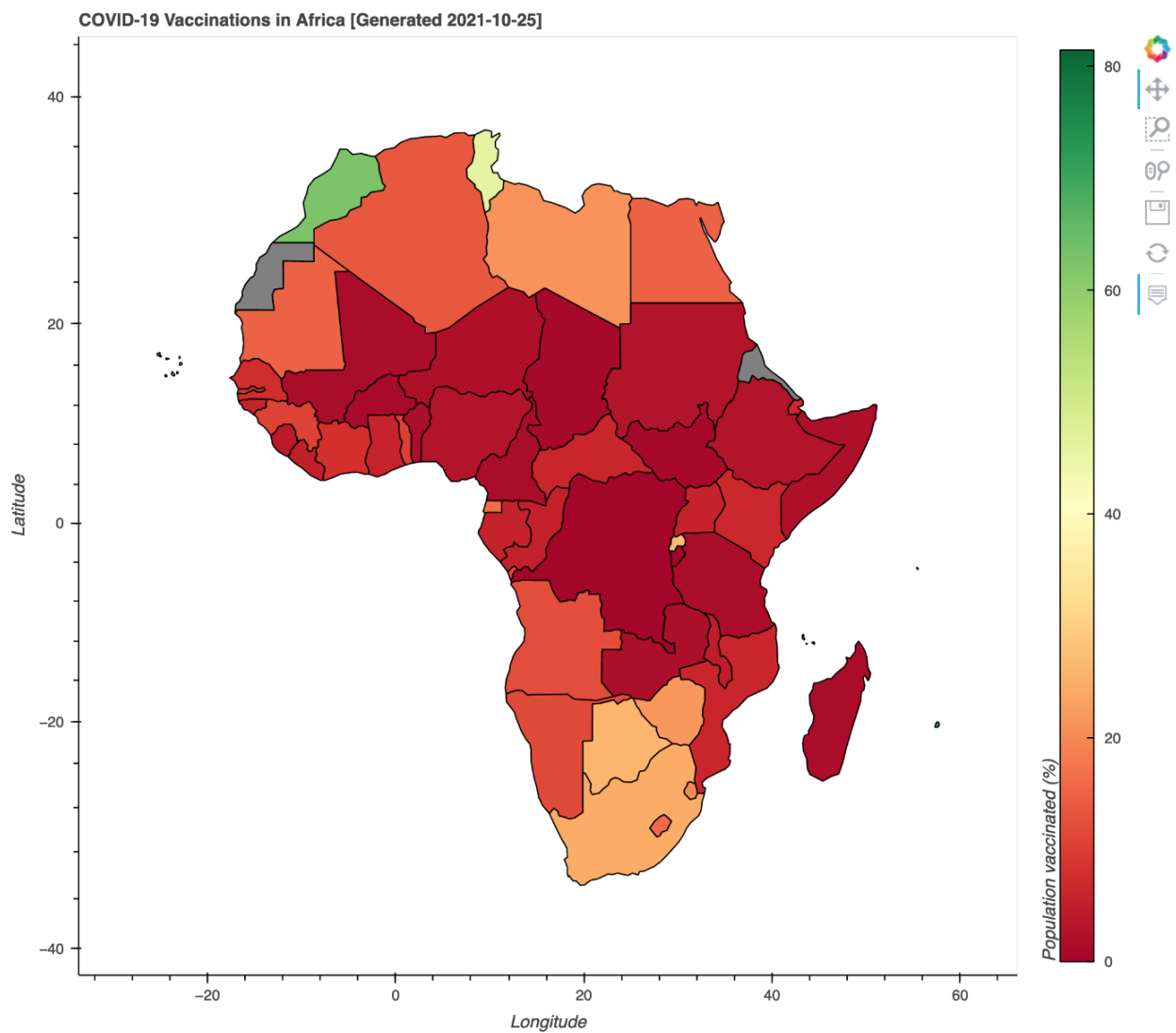
Figures and Supplemental Information

VacSafe Working Group Website

The VacSafe Working Group website houses publicly facing versions of these briefings, an interactive map that tracks COVID-19 vaccination rates and their correlates in Africa, and up-to-date information on the working group's convenings and projects. The website can be found at www.vacsafe.columbia.edu.

The interactive map is hosted here: <https://vacsafe.columbia.edu/content/vacsafe-africa-map>.

Figure 1: VacSafe Africa Map



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